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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,459	11/22/1999	Bruce M. Cameron SR.	72874.0113	8685

7590 06/03/2002

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 06/03/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/444,459

Applicant(s)

CAMERON ET AL.

Examiner

Louise N. Leary

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on amendment filed 3-11-2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-25 and 56-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-25 is/are allowed.
- 6) ☒ Claim(s) 56-58, 60-62, 67-68, 71-76, 79- 80 is/are rejected.
- 7) ☒ Claim(s) 59, 63-66, 69-70, 77-78, 81- is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

1. Claims 20-25, and 56-81 are pending in this application.

Claims 1-20, and 26-55 have been canceled per applicants' request.

2. Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 is indefinite because due to the recitation of the phrase "may be". The phrase "may be" does not particularly point out and distinctly claim the subject matter regarded as the invention. Correction is required to comply with US Patent practice.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-58, 60-62, 67-68, 71-76 and 79-80 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cook (US Patent 3,928,594).

Cook discloses a method of diagnosing the intensity of pain in a patient comprising determining the amount of cholinesterase in a biological sample from the patient. Also, Cook discloses methods for treating the symptoms and signs associated with demylinating processes or other conditions in man characterized by defective neural transmission with an acetylcholine-cholinesterase imbalance due to relative decrease in cholinesterase activity. Cook specifically describes multiple sclerosis as an example of a demylinating disease. Note the Abstract and column 2, lines 34-66. Cook further discloses methods for administering pharmaceutical compositions to alleviate pain associated with cholinesterase imbalance(s) in the patients with pathological central nervous system (i.e., brain and spine) or spinal cord conditions. Note column 5, lines 2-29, and column 6, lines 1-28. Thus, Cook discloses all the limitations claimed except for implicitly stating that a "predetermined pain marker amount" was used in the method.

However, with respect to the use of a "predetermined pain marker amount" in a comparison step, Cook discloses comparative evaluation was permitted during the diagnostic and therapeutic methods disclosed. See column 4, lines 2-5. It is noted that Cook discloses methods of diagnosing the intensity of pain perceived by a patient comprising determining the amount of neurotransmitter or cholinesterase, pharmaceutical compositions and methods for treating patients with pathological central nervous system (i.e., brain and spine) or spinal cord conditions which anticipates or renders obvious the present invention.

Therefore, the burden of proof is on applicant to show patentably distinct differences between the invention claimed and the subject matter claimed in the Cook disclosure.

4. Claims 59, 63-66, 69-70, 77-78, and 81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 21-25 are allowable over the prior art of record.

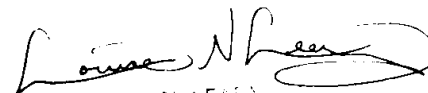
6. The Yang et al reference (Anesthesiology, V 88(2), p334, (1998) (Abstract Only) disclose a method for diagnosing pain in a patient and evaluated patients injected with acetylcholinesterase inhibitor and has been cited to further show the state of this art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEACH  
PRIMARY EXAMINER

May 28, 2002